Protocol Plain Language Summary

Clinical trial of MK-2870 in people with NSCLC whose tissue removed during surgery have signs of cancer (MK-2870-019)

Protocol Title: A Phase 3 Randomized Open-Label Study of Adjuvant Pembrolizumab With or Without MK-2870 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy Followed by Surgery

Why is this study needed?

Researchers are looking for new ways to treat **non-small cell lung cancer** (**NSCLC**). NSCLC is the most common type of lung cancer. Treatment for NSCLC usually includes chemotherapy and immunotherapy, such as **pembrolizumab**, then surgery to remove the cancer. **Chemotherapy** uses medicine to shrink or get rid of cancer cells. **Immunotherapy** is a treatment that helps the immune system fight cancer. Some people may also receive immunotherapy after surgery.

Researchers want to learn if adding **MK-2870 with pembrolizumab** (the study medications) after surgery can treat NSCLC for certain patients. MK-2870 is a **targeted therapy**, which is a treatment that works to control how specific types of cancer cells grow and spread. The goal of this study is to learn if people who receive pembrolizumab with MK-2870 after surgery are cancer free longer than people who receive pembrolizumab alone after surgery.

Who will take part in this study?

People with NSCLC who are 18 years old and older and:

- They are able to receive neoadjuvant treatment with immunotherapy in combination with chemotherapy pre-surgery. People who have already received pembrolizumab with chemotherapy followed by surgery prior to joining the study may be able to participate in the study.
- Tumors or lymph nodes removed during surgery have signs of cancer. **Lymph nodes** are small, bean-shaped organs that are part of the immune system.

There may be reasons that people cannot be in this study. The study doctor or staff will discuss these with them.

What treatments are being given during the study?

People will receive 2 or more of these through a needle into a vein as an intravenous (IV) infusion:

- **Chemotherapy** (pre-surgery)
- **Pembrolizumab**, the study medicine (pre-surgery and after surgery)
- **MK-2870**, the study medicine (after surgery)

How is this study designed?

There are 3 parts to this study: pre-surgery, surgery, and post-surgery**.** Researchers will review the tissue removed during surgery. People whose tumors and lymph nodes removed during surgery have signs of cancer, will have an equal chance of being assigned to receive either pembrolizumab with MK-2870 or pembrolizumab alone after surgery.

Pre-surgery period: Before surgery, people will receive **pembrolizumab and chemotherapy** every 3 weeks for 12 weeks.

Surgery period: Surgery will be performed to remove the cancer. After surgery, some people may require radiation therapy. **Radiation therapy** is a treatment that uses beams of high energy (like X-rays) to shrink or eliminate disease.

People whose tumors and lymph nodes removed during surgery have signs of cancer will continue to Post-surgery period of the study.

Post-surgery period: People will have an equal chance of being assigned to one of these groups:

- **Group A** will receive **pembrolizumab** every 6 weeks **with MK-2870** every 2 weeks for about 10 months
- **Group B** will receive **pembrolizumab alone** every 6 weeks for about 10 months

Both the people in the study and the researchers will know which treatment the person is getting (open-label). During the study, people will give urine and blood samples, have tumor and imaging tests, have physical examinations, and answer questions about how they are feeling. A person could be in this study for up to 10 years.

What are the goals of this study and how will they be measured?

Main goal	How it will be measured
To learn if the **disease-free survival (DFS)** of Group A is longer than Group B in Post-surgery period per central assessment	**DFS** is the length of time from the start of Post-surgery period until cancer comes back or death from any cause assessed by central study doctor
Other goals	**How they will be measured**
To learn about the **cancer response** of Group A compared to Group B in Post-surgery period for overall survival (OS), distant metastasis-free survival (DMFS), DFS per local assessment, lung cancer specific survival (LCSS)	Researchers will measure: • **OS** – the length of time that people live from the start of Post-surgery period until death from any cause • **DMFS** – the length of time from the start of Post-surgery period until the cancer spreads from where it started to other parts of the body or death from any cause • **DFS** – the length of time from the start of Post-surgery period until cancer comes back or death from any cause assessed by local study doctor • **LCSS** – the length of time that people live from the start of Post-surgery period until death from lung cancer
To learn about the **safety** and how well people **tolerate** pembrolizumab with MK-2870 in Post-surgery period	The number of people who: • Have an **adverse event** (AE) – an AE is a health problem that happens or worsens during a study • Stop treatment due to an AE
To compare the **quality of life (QoL)** of Group A to Group B in Post-surgery period	People will answer questions about their QoL. The questions are about how they are feeling, their ability to carry out daily tasks, and NSCLC symptoms**.** Researchers will measure the change in the scores during Post-surgery period.

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study. This study has an external group of experts who oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe or does not show benefit, the study can be stopped. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.